Docket No.: Bolton/1042

CERTIFICATION OF MAILING OR TRANSMISSION

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Signature

February 5, 2007
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applic. No. | : | 10/784,462 | Confirmation No: 8228 |
| Applicant | : | Humberto Berra, et al. | |
| Filed | : | February 23, 2004 | |
| Art Unit | : | Stent Graft | |
| Examiner | : | Brian E. Pellegrino | |
| Docket No. | : | Bolton/1042 | |
| Customer No.: | | 27316 | |

# LETTER

Hon. Commissioner for Patents,
Alexandria, VA 22313-1450

Sir:

The Notification of Non-Compliant Brief dated January 30, 2007 stated that "the appeal brief filed December 18, 2006 had several pages cut off, therefore, it needs to be resubmitted." Therefore, attorney for applicant attaches hereto a copy of the appeal brief filed on December 18, 2006 as requested.

The Patent and Trademark Office is hereby given authority to charge Deposit Account No, 503,836 of Gregory L. Mayback, P.A. for any fees due or any deficiencies of payments made for any purpose during the pendency of the above-identified application.

Respectfully submitted,

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Date: February 5, 2007
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Docket No.: BOLTON 1042

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office at 571.273.8300 on the date shown below.

By: Serene Keen Date: December 18, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

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|---|---|---|---|
| Applic. No. | : | 10/784,462 | Conf. No. 8228 |
| Applicant | : | Humberto Berra et al. | |
| Filed | : | February 23, 2004 | |
| Title | : | Stent Graft | |
| Group Art Unit | : | 3731 | |
| Examiner | : | Brian E. Pellegrino | |
| | | | |
| Docket No. | : | Bolton 1042 | |
| Customer No. | : | 27,316 | |

**Mail Stop Appeal Brief-Patents**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**BRIEF ON APPEAL**

Sir:

This is an appeal from the final rejection in the July 17, 2006 Office action, finally rejecting claims 1 to 6, 10 to 21 , 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97.

Appellants submit one copy of this *Brief on Appeal* pursuant to MPEP 1205.02. The fee for filing the *Brief on Appeal* in the amount of $500.00 is enclosed. Please charge any other fees that might be due to the Deposit Account of Mayback & Hoffman, P.A., No. 503,836.

Real Party in Interest:

This application is assigned to Bolton Medical, Inc., of Sunrise, Florida, USA. The assignment is on file under Reel 015257, Frame 0867, and Reel 015532, Frame 0234.

Related Appeals and Interferences:

No related appeals or interference proceedings are currently pending which would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

Status of Claims:

Claims 1 to 109 remain in the application.

Claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 are rejected and are under appeal.

Claims 7 to 9, 22, 23, 30 to 39, 61 to 64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94, and 98 to 109 have been withdrawn from examination.

Status of Amendments:

No claims were amended after the final Office action.

A *Response* under 37 CFR § 1.116 was filed on September 18, 2006, and, after discovering errors in that Response, a Supplemental Response was filed on October 6, 2006, after speaking with the Examiner that such a supplement was to be filed. The Examiner stated in an *Advisory Action* dated October 12, 2006, that the request for reconsideration had been considered but did not place the application in condition for allowance. In an attempt to point out clear errors in the Final rejection, Appellants conducted an interview with the Examiner, which interview was summarized in an Interview Summary mailed December 5, 2006.

Summary of the Claimed Subject Matter:

As stated in the first paragraph on page 1 of the specification of the instant application, line 10, the invention lies in the field of endoluminal blood vessel repairs. The invention specifically relates to a stent graft used for endoluminally repairing aneurysm and/or dissections of the thoracic transverse aortic arch, thoracic posterior aortic arch, and the descending thoracic portion of the aorta.

Appellants explained on page 23 of the specification, line 6, that the present invention provides a stent graft and delivery system that treats, in particular, thoracic aortic defects from the brachiocephalic level of the aortic arch distally to a level just superior to the celiac axis and provides an endovascular foundation for an anastomosis with the thoracic aorta, while providing an alternative method for partial/total thoracic aortic repair by excluding the vessel defect and making surgical repair of the aorta unnecessary. The stent graft of the present invention, however, is not limited to use in the aorta. It can be endoluminally inserted in any accessible artery that could accommodate the stent graft's dimensions.

Appellants outlined on page 23 of the specification, line 15, that, the stent graft according to the present invention provides various features that, heretofore, have not been applied in the art and, thereby, provide a vessel repair device that implants/conforms more efficiently within the natural or diseased course of the aorta, decreases the likelihood of vessel puncture, and increases the blood-tight vascular connection, and decreases the probability of graft mobility.

It is further stated on page 22 of the specification, line 5, that, the stent graft is implanted endovascularly before or during or in place of an open repair of the vessel (i.e., an arch, in particular, the ascending and/or descending portion of the aorta) through a delivery system described in detail below. The typical defects treated by the stent graft are aortic aneurysms, aortic dissections, and other diseases such as penetrating aortic ulcer, coarctation, and patent ductus arteriosus, related to the aorta. When endovascularly placed in the aorta, the stent graft forms a seal in the vessel and automatically affixes itself to the vessel with resultant effacement of the pathological lesion.

It is described on page 23 of the specification, line 5, that, FIG. 1 shows an improved stent graft 1 having a graft sleeve 10 and a number of stents 20. These stents 20 are, preferably, made of nitinol, an alloy having particularly special properties allowing it to rebound to a set configuration after compression, the rebounding property being based upon the temperature at which the alloy exists. For a detailed explanation of nitinol and its application with regard to stents, see, i.e., United States Patent Nos. 4,665,906, 5,067,957, and 5,597,378 to Jervis and to Gianturco.

Appellants outlined on page 23 of the specification, line 13, that the graft sleeve 10 is cylindrical in shape and is made of a woven graft material along its entire length. The graft material is, preferably, polyester, in particular, polyester referred to under the name DACRON®

or other material types like Expanded Polytetrafluoroethylene ("EPTFE"), or other polymeric based coverings. The tubular graft sleeve 10 has a framework of individual lumen-supporting wires each referred to in the art as a stent 20. Connection of each stent 20 is, preferably, performed by sewing a polymeric (nylon, polyester) thread around an entirety of the stent 20 and through the graft sleeve 10. The stitch spacings are sufficiently close to prevent any edge of the stent 20 from extending substantially further from the outer circumference of the graft sleeve 10 than the diameter of the wire itself. Preferably, the stitches have a 0.5 mm to 5 mm spacing.

As set forth on page 23, line 23, the stents 20 are sewn either to the exterior or interior surfaces of the graft sleeve 10. FIG. 1 illustrates all stents 20, 30 on the exterior surface 16 of the graft sleeve 10. In a preferred non-illustrated embodiment, the most proximal 23 and distal stents and a bare stent 30 are connected to the interior surface of the graft sleeve 10 and the remainder of the stents 20 is connected to the exterior surface 16. Another possible non-illustrated embodiment alternates connection of the stents 20, 30 to the graft sleeve 10 from the graft exterior surface to the graft interior surface, the alternation having any periodic sequence.

It is further stated on page 25 of the specification, line 7, that a stent 20, when connected to the graft sleeve 10, radially forces the graft sleeve 10 open to a predetermined diameter D. The released radial force creates a seal with the vessel wall and affixes the graft to the vessel wall when the graft is implanted in the vessel and is allowed to expand.

Appellants outlined in the last paragraph on page 25 of the specification that, typically, the stents 20 are sized to fully expand to the diameter D of the fully expanded graft sleeve 10. However, a characteristic of the present invention is that each of the stents 20 and 30 has a diameter larger than the diameter D of the fully expanded graft sleeve 10. Thus, when the stent graft 1 is fully expanded and resting on the internal surface of the vessel where it has been

placed, each stent 20 is imparting independently a radially directed force to the graft sleeve 10. Such pre-compression, as it is referred to herein, is applied (1) to ensure that the graft covering is fully extended, (2) to ensure sufficient stent radial force to make sure sealing occurs, (3) to affix the stent graft and prevent it from kinking, and (4) to affix the stent graft and prevent migration.

Appellants also outlined on page 25 of the specification, line 21, that, preferably, each of the stents 20 is formed with a single nitinol wire. Of course other biocompatible materials can be used, for example, stainless steel, biopolymers, cobalt chrome, and titanium alloys.

Appellants stated in the first paragraph of page 26 of the specification that the preferred shape of each stent 20 corresponds to what is referred in the art as a Z-stent, see, i.e., Gianturco (although the shape of the stents 20 can be in any form that satisfies the functions of a self-expanding stent). Thus, the wire forming the stent 20 is a ring having a wavy or sinusoidal shape. In particular, an elevational view orthogonal to the center axis 21 of the stent 20 reveals a shape somewhere between a triangular wave and a sinusoidal wave as shown in FIG. 2. In other words, the view of FIG. 2 shows that the stents 20 each have alternating proximal 22 and distal 24 apices. Preferably, the apices have a radius r that does not present too great of a point towards a vessel wall to prevent any possibility of puncturing the vessel, regardless of the complete circumferential connection to the graft sleeve 10. In particular, the radius r of curvature of the proximal 22 and distal 24 apices of the stent 20 are, preferably, equal. The radius of curvature r is between approximately 0.1 mm and approximately 3.0 mm, in particular, approximately 0.5 mm.

Appellants outlined on page 26, line 14, that another advantageous feature of a stent lies in extending the longitudinal profile along which the stent contacts the inner wall of a vessel. This longitudinal profile can be explained with reference to FIGS. 3 to 7.

Appellants explained on page 26, line 17, that prior art stents and stents according to the present invention are formed on mandrels 29, 29' by winding the wire around the mandrel 29, 29' and forming the apexes 22, 24, 32, 34 by wrapping the wire over non-illustrated pins that protrude perpendicular from the axis of the mandrel. Such pins, if illustrated, would be located in the holes illustrated in the mandrels 29, 29' of FIGS 4 and 6. Prior art stents are formed on a round mandrel 29 (also referred to as a bar). A stent 20' formed on a round mandrel 29 has a profile that is rounded (see FIG. 5). Because of the rounded profile, the stent 20' does not conform evenly against the inner wall of the vessel 2 in which it is inserted. This disadvantage is critical in the area of stent graft 1 seal zones -- areas where the ends of the graft 10 need to be laid against the inner wall of the vessel 2. Clinical experience reveals that stents 20' formed with the round mandrel 29 do not lie against the vessel 2; instead, only a mid-section of the stent 20' rests against the vessel 2, as shown in FIG. 5. Accordingly, when such a stent 20' is present at either of the proximal 12 or distal 14 ends of the stent graft 1, the graft material flares away from the wall of the vessel 2 into the lumen -- a condition that is to be avoided. An example of this flaring can be seen by comparing the upper and lower portions of the curved longitudinal profile of the stent 20' in FIG. 5 with the linear longitudinal profile of the vessel 2.

As furthermore stated on page 27 of the specification, line 11, to remedy this problem and ensure co-columnar apposition of the stent and vessel, stents 20 of the present invention are formed on a multiple-sided mandrel. In particular, the stents 20 are formed on a polygonal-shaped mandrel 29'. The mandrel 29' does not have sharp edges. Instead, it has flat sections and rounded edge portions between the respective flat sections. Thus, a stent formed on the mandrel 29' will have a cross-section that is somewhat round but polygonal, as shown in FIG. 3. The cross-sectional view orthogonal to the center axis 21 of such a stent 20 will have beveled or

rounded edges 31 (corresponding to the rounded edge portions of the mandrel 29') disposed between flat sides or struts 33 (corresponding to the flat sections of the mandrel 29').

Appellants disclosed on page 27, line 21, that, to manufacture the stent 20, apexes of the stents 20 are formed by winding the wire over non-illustrated pins located on the rounded portions of the mandrel 29'. Thus, the struts 33 lying between the apexes 22, 24, 32, 34 of the stents 20 lie flat against the flat sides of the mandrel 29'. When so formed on the inventive mandrel 29', the longitudinal profile is substantially less rounded than the profile of stent 20' and, in practice, is substantially linear.

It is also noted on page 28, line 3, that, for stents 20 having six proximal 22 and six distal 24 apices, the stents 20 are formed on a dodecahedron-shaped mandrel 29' (a mandrel having twelve sides), which mandrel 29' is shown in FIG. 6. A stent 20 formed on such a mandrel 29' will have the cross-section illustrated in FIG. 3.

Appellants discussed on page 28, line 7, that the fourteen-apex stent 20 shown in FIG. 7 illustrates a stent 20 that has been formed on a fourteen-sided mandrel. The stent 20 in FIG. 7 is polygonal in cross-section (having fourteen sides) and, as shown in FIG. 7, has a substantially linear longitudinal profile. Clinically, the linear longitudinal profile improves the stent's 20 ability to conform to the vessel 2 and press the graft sleeve 10 outward in the sealing zones at the extremities of the individual stent 20.

Moreover, appellants discussed on page 28, line 13, that another way to improve the performance of the stent graft 1 is to provide the distal-most stent 25 (i.e., downstream) on the graft 10 with additional apices and to give it a longer longitudinal length (i.e., greater amplitude) and/or a longer circumferential length. When a stent 25 having a longer circumferential length is sewn to a graft, the stent graft 1 will perform better clinically. The improvement, in part, is due

to a need for the distal portion of the graft material 10 to be pressed firmly against the wall of the vessel. The additional apices result in additional points of contact between the stent graft 1 and vessel wall, thus ensuring better apposition to the wall of the vessel and better sealing of the graft material 10 to the vessel. The increased apposition and sealing substantially improves the axial alignment of the distal end 14 of the stent graft 1 to the vessel. As set forth above, each of the stents 20 and 30 has a diameter larger than the diameter D of the fully expanded graft sleeve 10. Thus, if the distal stent 25 also has a diameter larger than the diameter D, it will impart a greater radial bias on all 360 degrees of the corresponding section of the graft than stents not having such an oversized configuration.

Appellants further disclosed on page 28 of the specification, line 13, that another way to improve the performance of the stent graft 1 is to provide the distal-most stent 25 (i.e., downstream) on the graft 10 with additional apices and to give it a longer longitudinal length (i.e., greater amplitude) and/or a longer circumferential length. When a stent 25 having a longer circumferential length is sewn to a graft, the stent graft 1 will perform better clinically. The improvement, in part, is due to a need for the distal portion of the graft material 10 to be pressed firmly against the wall of the vessel. The additional apices result in additional points of contact between the stent graft 1 and vessel wall, thus ensuring better apposition to the wall of the vessel and better sealing of the graft material 10 to the vessel. The increased apposition and sealing substantially improves the axial alignment of the distal end 14 of the stent graft 1 to the vessel. As set forth above, each of the stents 20 and 30 has a diameter larger than the diameter D of the fully expanded graft sleeve 10. Thus, if the distal stent 25 also has a diameter larger than the diameter D, it will impart a greater radial bias on all 360 degrees of the corresponding section of the graft than stents not having such an oversized configuration.

It is further outlined on page 29, line 4, that, a typical implanted stent graft 1 typically does not experience a lifting off at straight portions of a vessel because the radial bias of the stents acting upon the graft sleeve give adequate pressure to align the stent and graft sleeve with the vessel wall. However, when a typical stent graft is implanted in a curved vessel (such as the aorta), the distal end of the stent graft 1 does experience a lift off from the vessel wall. The increased apposition and sealing of the stent graft 1 according to the present invention substantially decreases the probability of lift off because the added height and additional apices enhance the alignment of the stent graft perpendicular to the vessel wall as compared to prior art stent grafts (no lift off occurs).

Appellants discussed on page 30 of the specification, line 4, that, to increase the security of the stent graft 1 in a vessel, the stent graft 1 is provided, preferably, only at the proximal end 12 of the graft sleeve 10, with an exposed or bare stent 30 -- proximal meaning that it is attached to the portion of the graft sleeve 10 from which the blood flows into the sleeve, i.e., blood flows from the bare stent 30 and through the sleeve 10 to the left of FIG. 1. The bare stent 30 is not limited to being attached at the proximal end 12. Another non-illustrated bare stent can be attached similarly to the distal end 14 of the graft sleeve 10.

Appellants also explained on page 30 of the specification, line 11, that significantly, the bare stent 30 is only partially attached to the graft sleeve 10. Specifically, the bare stent 30 is fixed to the graft sleeve 10 only at the distal apices 34 of the bare stent 30. Thus, the bare stent 30 is partially free to extend the proximal apices 32 away from the proximal end of the graft sleeve 10.

It is furthermore outlined on page 31, first line, that the bare stent 30 has various properties, the primary one being to improve the apposition of the graft material to the contour

of the vessel wall and to align the proximal portion of the graft covering in the lumen of the arch and provide a blood-tight closure of the proximal end 12 of the graft sleeve 10 so that blood does not pass between the vascular inside wall and outer surface 16 of the sleeve 10 (endoleak).

In addition, appellants stated on page 32 of the specification, lien 19, that, because the vessel moves constantly, and due to the constantly changing pressure imparted by blood flow, any stent graft placed in the vessel has the natural tendency to migrate downstream. This is especially true when the stent graft 1 has graft sleeve segments 18 with lengths defined by the separation of the stents on either end of the segment 18, giving the stent graft 1 an accordion, concertina, or caterpillar-like shape. When such a shape is pulsating with the vessel and while hemodynamic pressure is imparted in a pulsating manner along the stent graft from the proximal end 12 to the downstream distal end 14, the stent graft 1 has a tendency to migrate downstream in the vessel. It is desired to have such motion be entirely prohibited.

Appellants discussed on page 33 of the specification, line 5, that support along a longitudinal extent of the graft sleeve 10 assists in preventing such movement. Accordingly, as set forth above, prior art stent grafts have provided longitudinal rods extending in a straight line from one stent to another.

Appellants also disclosed in the last paragraph on page 33 of the specification, line 8, that the present invention, however, provides a longitudinal, spiraling/helical support member 40 that, while extending relatively parallel to the longitudinal axis 11 of the graft sleeve 10, is not aligned substantially parallel to a longitudinal extent of the entirety of the stent graft 1 as done in the prior art. "Relatively parallel" is referred to herein as an extent that is more along the longitudinal axis 11 of the stent graft 1 than along an axis perpendicular thereto.

It is further explained on page 33 of the specification, line 14, that specifically, the longitudinal support member 40 has a somewhat S-turn shape, in that, a proximal portion 42 is relatively parallel to the axis 11 of the graft sleeve 10 at a first degree 41 (being defined as a degree of the 360 degrees of the circumference of the graft sleeve 10), and a distal portion 44 is, also, relatively parallel to the axis 11 of the tube graft, but at a different second degree 43 on the circumference of the graft sleeve 10. The difference between the first and second degrees 41, 43 is dependent upon the length L of the graft sleeve 10. For an approximately 20 cm (approx. 8") graft sleeve, for example, the second degree 43 is between 80 and 110 degrees away from the first degree 41, in particular, approximately 90 degrees away. In comparison, for an approximately 9 cm (approx. 3.5") graft sleeve, the second degree 43 is between 30 and 60 degrees away from the first degree 41, in particular, approximately 45 degrees away. As set forth below, the distance between the first and second degrees 41, 43 is also dependent upon the curvature and the kind of curvature that the stent graft 1 will be exposed to when in vivo.

Appellants also explained on page 34 of the specification, line 5, that the longitudinal support member 40 has the curved intermediate portion 46 between the proximal and distal portions 42, 44. By using the word "portion" it is not intended to mean that the rod is in three separate parts (of course, in a particular configuration, a multi-part embodiment is possible). A preferred embodiment of the longitudinal support member 40 is a single, one-piece rod made of stainless steel, cobalt chrome, nitinol, or polymeric material that is shaped as a fully curved helix 42, 44, 46 without any straight portion. In an alternative stent graft embodiment, the proximal and distal portions 42, 44 can be substantially parallel to the axis 11 of the stent graft 1 and the central portion 46 can be helically curved.

As outlined on page 34 of the specification, line 14, that one way to describe the preferred curvature embodiment of the longitudinal support member 40 can be using an analogy of asymptotes. If there are two asymptotes extending parallel to the longitudinal axis 11 of the graft sleeve 10 at the first and second degrees 41, 43 on the graft sleeve 10, then the proximal portion 42 can approach be on the first degree 41 or extend approximately asymptotically to the first degree 41 and the distal portion 44 can be on the second degree 43 or extend approximately asymptotically to the second degree 43. Because the longitudinal support member 40 is one piece in a preferred embodiment, the curved portion 46 follows the natural curve formed by placing the proximal and distal portions 42, 44 as set forth herein.

Appellants disclosed on page 31 of the specification, last paragraph, that, in such a position, the curved longitudinal support member 40 has a centerline 45 (parallel to the longitudinal axis 11 of the graft sleeve 10 halfway between the first and second degrees 41, 43 on the graft sleeve 10). In this embodiment, therefore, the curved portion intersects the centerline 45 at approximately 20 to 40 degrees in magnitude, preferably at approximately 30 to 35 degrees.

It is furthermore stated on page 35 of the specification, line 6, that another way to describe the curvature of the longitudinal support member can be with respect to the centerline 45. The portion of the longitudinal support member 40 between the first degree 41 and the center line 45 is approximately a mirror image of the portion of the longitudinal support member 40 between the second degree 43 and the center line 45, but rotated 180 degrees around an axis orthogonal to the center line 45. Such symmetry can be referred to herein as "reverse-mirror symmetrical."

As outlined on page 35 of the specification, line 12, that the longitudinal support member 40 is, preferably, sewn to the graft sleeve 10 in the same way as the stents 20. However, the longitudinal support member 40 is not sewn directly to any of the stents 20 in the proximal portions of the graft. In other words, the longitudinal support member 40 is independent of the proximal skeleton formed by the stents 20. Such a configuration is advantageous because an independent proximal end creates a gimbal that endows the stent graft with additional flexibility. Specifically, the gimbaled proximal end allows the proximal end to align better to the proximal point of apposition, thus reducing the chance for endoleak. The additional independence from the longitudinal support member allows the proximal fixation point to be independent from the distal section that is undergoing related motion due to the physiological motion of pulsutile flow of blood. Also in a preferred embodiment, the longitudinal support member 40 is pre-formed in the desired spiral/helical shape (counter-clockwise from proximal to distal), before being attached to the graft sleeve 10.

Appellants stated on page 36 of the specification, line 3, that because vessels receiving the stent graft 1 are not typically straight, the final implanted position of the stent graft 1 will, most likely, be curved in some way. In prior art stent grafts (which only provide longitudinally parallel support rods), there exist, inherently, a force that urges the rod, and, thereby, the entire stent graft, to the straightened, natural shape of the rod. This force is disadvantageous for stent grafts that are to be installed in an at least partly curved manner.

As discussed on page 36 of the specification, line 9, the curved shape of the longitudinal support member 40 according to the present invention eliminates at least a majority, or substantially all, of this disadvantage because the longitudinal support member's 40 natural shape is curved and, therefore, imparts less of a force, or none at all, to straighten the

longitudinal support member 40, and, thereby, move the implanted stent graft in an undesirable way. At the same time, the curved longitudinal support member 40 negates the effect of the latent kinetic force residing in the aortic wall that is generated by the propagation of the pulse wave and systolic blood pressure in the cardiac cycle, which is, then, released during diastole.

Appellants disclosed on page 36 of the specification, line 18, that, in a preferred embodiment, the longitudinal support member 40 can be curved in a patient-customized way to accommodate the anticipated curve of the actual vessel in which the graft will be implanted. Thus, the distance between the first and second degrees 41, 43 will be dependent upon the curvature and the kind of curvature that the stent graft 1 will be exposed to when in vivo. As such, when implanted, the curved longitudinal support member 40 will, actually, exhibit an opposite force against any environment that would alter its conformance to the shape of its resident vessel's existing course(es).

It is also outlined on page 37, line 3, that, preferably, the support member 40 is sewn, in a similar manner as the stents 20, on the outside surface 16 of the graft sleeve 10.

Appellants stated on page 37 of the specification, line 5, that in prior art support rods, the ends thereof are merely a terminating end of a steel or nitinol rod and are, therefore, sharp. Even though these ends are sewn to the tube graft in the prior art, the possibility of tearing the vessel wall still exists. It is, therefore, desirable to not provide the support rod with sharp ends that could puncture the vessel in which the stent graft is placed.

Appellants also outlined on page 37 of the specification, line 10, that, the two ends of the longitudinal support member 40 of the present invention do not end abruptly. Instead, each end of the longitudinal support member loops 47 back upon itself such that the end of the longitudinal support member along the axis of the stent graft is not sharp and, instead, presents

an exterior of a circular or oval shape when viewed from the ends 12, 14 of the graft sleeve 10. Such a configuration substantially prevents the possibility of tearing the vessel wall and also provides additional longitudinal support at the oval shape by having two longitudinally extending sides of the oval 47.

Appellants furthermore explained on page 37, line 18, that, in another embodiment, the end of the longitudinal support member may be connected to the second proximal stent 28 and to the most distal stent. This configuration would allow the longitudinal support member to be affixed to stent 28 (see FIG. 1) and the most distal stent for support while still allowing for the gimbaled feature of the proximal end of the stent graft to be maintained.

It is also stated on page 23, line 23, that a significant feature of the longitudinal support member 40 is that the ends of the longitudinal support member 40 may not extend all the way to the two ends 12, 14 of the graft sleeve 10. Instead, the longitudinal support member 40 terminates at or prior to the second-to-last stent 28 at the proximal end 12, and, if desired, prior to the second-to-last stent 28' at the distal end 14 of the graft sleeve 10. Such an ending configuration (whether proximal only or both proximal and distal) is chosen for a particular reason -- when the longitudinal support member 40 ends before either of the planes defined by cross-sectional lines 52, 52', the sleeve 10 and the stents 20 connected thereto respectively form gimbaled portions 50, 50'. In other words, when a grasping force acting upon the gimbaled ends 50, 50' moves or pivots the cross-sectional plane defining each end opening of the graft sleeve 10 about the longitudinal axis 11 starting from the planes defined by the cross-sectional lines 52, 52', then the moving portions 50, 50' can be oriented at any angle $\gamma$ about the center of the circular opening in all directions (360 degrees), as shown in FIG. 8. The natural gimbal, thus, allows the ends 50, 50' to be inclined in any radial direction away from the longitudinal axis 11.

Appellants disclosed on page 38, line 15, that, among other things, the gimbaled ends 50, 50' allow each end opening to dynamically align naturally to the curve of the vessel in which it is implanted. A significant advantage of the gimbaled ends 50, 50' is that they limit propagation of the forces acting upon the separate parts. Specifically, a force that, previously, would act upon the entirety of the stent graft 1, in other words, both the end portions 50, 50' and the middle portion of the stent graft 1 (i.e., between planes 52, 52'), now principally acts upon the portion in which the force occurs. For example, a force that acts only upon one of the end portions 50, 50' substantially does not propagate into the middle portion of the stent graft 1 (i.e., between planes 52, 52'). More significantly, however, when a force acts upon the middle portion of the stent graft 1 (whether moving longitudinally, axially (dilation), or in a torqued manner), the ends 50, 50', because they are gimbaled, remain relatively completely aligned with the natural contours of the vessel surrounding the respective end 50, 50' and have virtually none of the force transferred thereto, which force could potentially cause the ends to grate, rub, or shift from their desired fixed position in the vessel. Accordingly, the stent graft ends 50, 50' remain fixed in the implanted position and extend the seating life of the stent graft 1.

As furthermore explained on page 40, line 8, another advantage of the longitudinal support member 40 is that it increases the columnar strength of the graft stent 1. Specifically, the material of the graft sleeve can be compressed easily along the longitudinal axis 11, a property that remains true even with the presence of the stents 20 so long as the stents 20 are attached to the graft sleeve 10 with a spacing between the distal apices 24 of one stent 20 and the proximal apices 22 of the next adjacent stent 20. This is especially true for the amount of force imparted by the flow of blood along the extent of the longitudinal axis 11. However, with the longitudinal support member 40 attached according to the present invention, longitudinal

strength of the stent graft 1 increases to overcome the longitudinal forces imparted by blood flow.

Finally, appellants note on page 39 of the specification, line 18, that another benefit imparted by having such increased longitudinal strength is that the stent graft 1 is further prevented from migrating in the vessel because the tube graft is not compressing and expanding in an accordion-like -- movement that would, inherently, cause graft migration.

References Cited:

| | | |
|---|---|---|
| US 2003/883005 | Van Schie et al. | May 8, 2003 |
| 6,099,558 | White et al. | Aug. 8, 2000 |
| 6,464,719 | Jayaraman | Oct. 15, 2002 |

Grounds of Rejection to be Reviewed on Appeal:

1) Whether or not the drawings show the feature of the support member being connected to the graft without touching the stents;

2) Whether or not U.S. Patent Publication No. 2003/883,005 to Van Schie et al. (hereinafter "Van Schie") fully anticipates claims 1, 2, 5, 6, 10, 11, 14, 15 to 17, 20, 21, 24 to 29, 40 to 42, 44 to 47, 49, 51, 55, 57, 59, 65 to 67, 70 to 72, 75 to 77, 85 to 87, 90 to 92, and 95 to 97 under 35 U.S.C. § 102(b); and

3) Whether or not claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 are obvious over U.S. Patent No. 6,099,558 to White et al.

(hereinafter "White") in view of U.S. Patent No. 6,464,719 to Jayaraman under 35 U.S.C. § 103(a) and whether or not White and Jayaraman are properly combined under Section 103.

**Grouping of Claims:**

Claims 1 to 109 remain in the application.

Claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 are subject to examination.

Claims 7 to 9, 22, 23, 30 to 39, 61 to 64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94, 98 to 109 have been withdrawn from examination.

Claims 1, 15, 16, 18, 20, 25, and 28 are independent.

Claims 2 to 6, 10 to 14, 40, 47, 48, and 65 to 67 depend on claim 1.

Claim 41, 49, 50, and 70 to 72 depend on claim 15.

Claim 17, 42, 51, 52, and 75 to 77 depend on claim 16.

Claim 19, 43, 53, 54, and 80 to 82 depend on claim 18.

Claims 21, 24, 44, 55, 56, and 85 to 87 depend on claim 20.

Claims 26, 27, 45, 57, 58, and 90 to 92 depend on claim 25.

Claims 29, 46, 59, 60, and 95 to 97 depend on claim 28.

Some of the dependent claims are argued separately from their respective independent claims. Such dependent claims do not stand or fall with their respective independent claims. Where dependent claims are not argued separately, such dependent claims stand or fall with their respective independent claim.

Some of the claims are argued together for the sake of clarity and to eliminate redundancy of the arguments set forth herein.

**ARGUMENT:**

This is an appeal from a Final Office action dated July 17, 2006, in which the Examiner:

(1) objected to the drawings;

(2) rejected, under 35 U.S.C. § 102(b), claims 1, 2, 5, 6, 10, 11, 14, 15 to 17, 20, 21, 24 to 29, 40 to 42, 44 to 47, 49, 51, 55, 57, 59, 65 to 67, 70 to 72, 75 to 77, 85 to 87, 90 to 92, and 95 to 97 as being fully anticipated by Van Schie et al.; and

(3) rejected, under 35 U.S.C. § 103(a), claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 as being obvious over White and Jayaraman.

Each of these items will be addressed in turn.

**A. The Drawings Clearly Show that the Support Member is Connected to the Graft Without Touching the Stents**

On page 2 of the final Office action, the Examiner objected to the drawings and requested the addition of a new drawing. More specifically, the Examiner states that "the support member connected to the graft without touching the stents or touching one of the stents must be shown."

The Examiner, after being asked in both responses to the first and final Office actions, did not specify to which claims these features relate. This, alone, should be reason enough to overcome the objection and warrant reversal of the objection. Assuming that the objection relates to claims 26, 27, and 28, the text of these claims are set forth in their entirety:

> 26. The vascular repair device according to claim 25, wherein said support member is connected to said graft body without touching said inner stents.
>
> 27. The vascular repair device according to claim 25, wherein said support member is connected to said graft body to touch at least one of said inner stents.
>
> 28. A vascular repair device, comprising:
>
> a tubular graft body having first and second ends;
>
> a structural framework having at least three stents, two of said stents being connected to said tubular graft body adjacent said first end, said two stents being separated from one another on said graft body to define an outer stent and an inner stent, a third of said stents being connected to said tubular graft body adjacent said second end; and

> a longitudinal support member having two ends and being connected to said graft body between said inner stent and said third stent without touching said inner stent and said third stent.

FIG. 1 clearly shows these features. Thus, the Examiner's requirement cannot be upheld.

It is noted that the inner stents mentioned in claims 25 to 28 can be any of the stents between lines 52 and 52' in FIG. 1. Page 24, lines 23 and 24, of the specification of the instant application provides that the "stents 20 are sewn **either to** the exterior or interior surfaces of the graft sleeve 10." (Emphasis added by appellants.) Further, page 35, lines 12 to 16, provides that the "longitudinal support member 40 is, preferably, sewn to the graft sleeve 10 **in the same way as the stents 20**. However, the longitudinal support member 40 **is not sewn directly to any of the stents 20** in the proximal portions of the graft. **In other words, the longitudinal support member 40 is independent of the proximal skeleton formed by the stents 20.**" (Emphasis added by appellants.) FIG. 1 illustrates the stents being sewn on the outside *or* the inside of the graft sleeve and the support member 40 also being sewn on either the outside *or* the inside of the graft sleeve. This support member is not sewn directly to any of the stents. Therefore, at least 8 combinations of the stent-to-graft sleeve and support member-to-graft sleeve are possible – all of which are all illustrated in FIG. 1. Having a figure that shows 8 possible connection combinations is more than sufficient to provide support for the features in claims 26 to 28, and adding other drawing figures to show the interior and exterior surfaces of the graft 10 would be redundant.

Because the cited features are illustrated in the drawings, no new drawing figure is needed and the Examiner's objection must be withdrawn.

**B. Summary of the Claims at Issue.**

In brief summary, the present invention is limited to claims for a vascular repair device, sometimes referred to as a stent or a stent graft. There are seven independent claims at issue, each of which is summarized here. These claims are discussed in greater detail later within the Argument section of this Brief.

Claim 1 calls for, *inter alia*, a vascular repair device, including:

> a tubular graft body having a longitudinal axis; and
>
> a curved longitudinal support member having a centerline parallel to the longitudinal axis and being substantially symmetrical with respect to the longitudinal axis.

Claim 15 calls for, *inter alia*, a vascular repair device, including:

> a tubular graft body having a longitudinal axis;
>
> a structural framework having at least two stents connected to the tubular graft body; and
>
> a curved longitudinal support member connected to the graft body independent of the structural framework, having a centerline parallel to the longitudinal axis, and being substantially symmetrical with respect to the longitudinal axis.

Each of claims 1 and 15 provides a curved longitudinal support member having a centerline parallel to the longitudinal axis and being substantially symmetrical with respect to the longitudinal axis.

Claim 16 calls for, *inter alia*, a vascular repair device, including:

> a tubular graft body;
>
> a longitudinal support member having two ends, at least one of the ends having a curved longitudinal extremity.

This claim provides that at least one of the ends of the support member has a curved shape. This is in contrast to prior art support members (most of which are wires) that all have ends that abruptly end.

Claim 18 calls for, *inter alia*, a vascular repair device, including:

> a structural framework having at least two stents each respectively connected to the tubular graft body adjacent a proximal end and a distal end of the graft body and defining a separation distance therebetween; and
>
> a longitudinal support member shorter than the separation distance and being connected to the graft body between the two stents to form a gimbal at at least one of the proximal and distal ends of the graft body.

This claim provides a gimbal on at least one of the ends – a feature that has never been suggested by the prior art.

Claims 20, 25, and 28 have similar features and, for the sake of brevity, will not be repeated in the text below. Claim 20 calls for, *inter alia*, a vascular repair device, including:

a tubular graft body having a proximal end and a distal end;

a structural framework having at least two pairs of stents each respectively connected to the graft body adjacent the proximal end and the distal end, the stents of each of the pairs of stents being separated from one another at the graft body to define a respective outer stent and a respective inner stent; and

a longitudinal support member connected to the graft body and extending between:

at least the inner stent of a first of the two pairs of stents; and

at least the outer stent of a second of the two pairs of stents.

Claim 25, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

a curved longitudinal support member having two ends and being connected to the graft body between both of the inner stents of the two pairs of stents.

Claim 28, as originally supplied, calls for, *inter alia*, a vascular repair device, including:

a structural framework having two stents connected to a tubular graft body adjacent a first end to define an outer stent and an inner stent and a third stent connected to the tubular graft body adjacent a second end; and

a longitudinal support member connected to the graft body between the inner stent and the third stent without touching the inner stent and the third stent.

Simply put, the support member of the present invention **ends prior to** at least one stent of the structural framework so that a gimbal is present at either or both ends of the vascular repair device (as explained in detail in the specification as set forth above). Such a gimbal has never been provided by prior art vascular repair devices.

These are the only independent claims at issue on this appeal. All the remaining claims are dependent on one or the other of these independent claims.

### C. Van Schie Does Not Anticipate Claims 1, 15, 16, 20, 25, or 28 under Section 102(b).

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (emphasis added by appellants). According to the single source rule, all the claim's limitations must be contained in a single reference, *see. e.g., Brown v. 3M*, 265 F.3d 1349, 1351 (Fed.Cir.2001), and the reference "must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed.Cir.2002).

As will be described below, Van Schie cannot anticipate the invention set forth in any of claims 1, 15, 16, 18, 20, 25, or 28.

#### 1. The Entirety of the Section 102 Rejection is Set Forth in 12 Lines of Text

It is noted that the **entirety** of the Examiner's argument -- which attempts to reject all of the various and different features in each of claims 1, 15, 16, 18, 20, 25, and 28 -- is contained in 158 words of twelve lines on page 3 of the final Office action (which is just a little more than the eight lines of rejection of these same claims in the first Office action).

Appellant takes these twelve lines in the following text and attempts to match them to the independent claims to understand the Examiner's attempt to argue that every one of the various and diverse features of claims 1, 15, 16, 18, 20, and 25 are completely anticipated:

> "Fig. 2 shows a stent graft having a plurality of stents with the middle stents being considered as inner stents and a tubular graft body surrounding the stents." **Possibly claims 18, 20, 25, and 28**;
>
> "It can also be seen there is a curved longitudinal support member 8 connected to the graft independent of the stents and has rounded ends 9, 10." **Possibly claims 1 and 15**;
>
> "Van Schie et al. disclose the support member is a polymer or metal and is preset, paragraph 45 [sic]." **No Claim;**
>
> "The support member is substantially symmetrical with respect to a centerline that is about the middle of the device going around the circumference." **Possibly claim 1 and 15;**
>
> "It can be construed that the rounded ends are curved extremeties." **Possibly claim 16; and**
>
> "With respect to the new limitation of claims 1 and 15 that the curved support member has a centerline parallel to the longitudinal axis, it can be said that the center point of any arc that lies along a longitudinal axis of a longitudinally extending conduit would be parallel to the longitudinal axis." **Possibly claims 1 and 15.**

The Examiner has rejected every one these independent claims based only upon these arguments, which allegedly compare and set forth the disclosure of each and every one of the features in claims 1, 15, 16, 18, 20, 25, and 28 pursuant to the required standards of comparison under Section 102. A mere examination of these alleged comparisons reveals that the rejections are each without sufficient specificity to be supported under any standard of review.

**2. Van Schie Does Not Disclose the Feature of Claims 18, 20, 25, and 28**

As set forth above, independent claims 18, 20, 25, and 28 relate to a gimbaled structure present on at least one of the ends of a vascular repair device (i.e., stent graft). This structure is discussed at length in the specification and, specifically, with regard to FIG. 8. It is further noted that one having ordinary skill in the art would know the meaning of a gimbal as used within the context of the present invention. Therefore, any argument suggesting that this structural feature is indefinite must be rejected.

The Examiner's arguments are entirely devoid of comments related to gimbals or having the support member end at a position with respect to a given stent. The only remark by the Examiner that could possibly relate to these claims is that "Fig. 2 shows a stent graft having a plurality of stents with the middle stents being considered as inner stents and a tubular graft body surrounding the stents."

Absolutely none of the Examiner's arguments mention or even suggest a gimbaled structure. There is a good reason for this absence – Van Schie does not hint at a gimbaled feature, let alone make a specific reference to the required gimbaled structure of claims 18, 20, 25, and 28 as is necessary to support a Section 102 rejection. The utter silence within the Examiner's Section 102 rationale requires the reversal of the Section 102 rejection of these claims.

Appellant believes that it may be helpful to the Board to clarify why the gimbal feature (illustrated in detail with regard to FIG. 8, for example) is present in claims 20, 25, and 28 in addition to claim 18 (which uses the word "gimbal" in the claim). As is clearly set forth

beginning at page 35 in the specification, and, particularly at the bottom of page 37 to the top of page 39 -- it is the structure of having a longitudinal support member **terminate at or prior to** a stent at the proximal end of the stent graft that **creates the gimbal** at the proximal end thereof (and, if desired at the distal end, prior to a stent at the distal end of the graft sleeve). Claims 20, 25, and 28 clearly set forth such a structure.

Van Schie discloses no embodiment where a longitudinal member extends only between the inner stents or the outer stents. In every Van Schie embodiment discussed, what the Examiner is referring to as a "longitudinal member" extends past at least a part of both of the extreme stents. Thus, Van Schie cannot suggest, let alone specifically disclose, the features of claims 18, 20, 25, or 28.

Specifically with regard to claim 25, Van Schie does not show (or suggest) having a longitudinal support member extending no further than both of the two inner stents of two of the extreme pairs of stents.

With regard to claim 28, Van Schie does not show or suggest a longitudinal support member extending no further than one of the two inner stents on one end and no further than a third stent on the other end.

For all of these reasons, Van Schie cannot be said to anticipate the features of claims 18, 20, 25, or 28.

### 3. Van Schie Does Not Disclose the Features of Claims 1, 15, or 16

Each of claims 1, 15, and 16 provide features relevant to a longitudinal support member – a structure that, by definition, provides support in the *longitudinal* direction, in other words, *prevents* compression or expansion.

Claim 16 provides that the "longitudinal support member [has] two ends, at least one of [which] having a curved longitudinal extremity" and claims 1 and 15 provide that the "curved longitudinal support member [has] a centerline parallel to said longitudinal axis, said support member being substantially symmetrical with respect to said longitudinal axis." These claims will be addressed in this order.

In the rejection of claim 16, the Examiner argues that the "rounded ends" – which the Examiner says are labeled with reference numerals 9 and 10 -- anticipate the curved longitudinal extremity of claim 16. This specious argument cannot be accepted. In the entire Van Schie disclosure, reference numerals 9 and 10 are mentioned only twice -- in paragraphs [0045] and [0046]. Nowhere does Van Schie indicate that this numbered feature is anything other than a **fastening point** (for the elastic rubber/shape memory metal); in other words, it is a *location*, it is not a structure. Merely because FIG. 2 illustrates this fastening point as a dot does not mean that it is an end "having a curved longitudinal extremity" as set forth in Claim 16, and shown, for example, in FIGS. 1 and 9 of the present application.

The examiner contends that the ends 9, 10 are "rounded" and, therefore, the material 8 is has a "curved longitudinal extremity." There is no disclosure or suggestion in Van Schie to support

this conclusion. In fact, Van Schie only refers to 9 and 10 as points in space and not structures of the Van Schie invention. Thus, only a conclusion *opposite* to that proffered by the Examiner can be supported because the location described with reference numerals 9 and 10 are not part of the elastic material 8. If they are not part of the elastic material, then they cannot be a "curved longitudinal extremity" of a "longitudinal support member" as required in claim 16.

Because no embodiment of the supporting feature of Van Schie has a **longitudinal extremity** that is curved, Van Schie cannot be said to anticipate the features of claim 16.

With respect to claims 1 and 15, the Examiner merely states -- without any support whatsoever -- that the Van Schie device includes a support member with "centerline parallel to said longitudinal axis" and "substantially symmetrical with respect to said longitudinal axis" of the graft body. Importantly, the exact language of the Examiner is noted:

> The support member is substantially symmetrical with respect to a centerline that is about the middle of the device **going around the circumference**. (Emphasis supplied by appellants.)

Why the Examiner analogizes the features of claims 1 and 15 to a circumferential plane of the graft body is not understood by appellants when the claim language does not refer to such a plane. The specification describes, in more than sufficient detail, that symmetry is with regard to the longitudinal axis; in other words on either side of the longitudinal axis, not about a circumference! Further, the claim, itself, relates the symmetry to the longitudinal axis.

The symmetry of the support member in claims 1 and 15 is with respect to the longitudinal axis of the graft body, in other words, what is referred to as the "centerline" (labeled with reference numeral 45 in the specification). Symmetry in the context of the present application is defined as having at least portion of the support member on either side of the centerline 45, not constantly and permanently along the centerline thereof. In other words, the support member 40 of the invention of the present application has some portions at a distance from the centerline 45, with these portions being symmetrical with respect to the longitudinal axis. The explanation of symmetry is set forth clearly in the specification at 35, for example. See also page 55.

Patent law permits appellants to be their own lexicographers. See, i.e., Fromson v. Advance Offset Plate, Inc. et al., 219 U.S.P.Q. 1137, 1140 (Fed. Cir. 1983), and Multiform Desiccants, Inc. v. Medzam, Ltd., 45 USPQ2d 1429 (Fed. Cir. 1998). With such authorization, appellants defined the meaning of "centerline" and "symmetrical" in the instant application as they are used in the claims. Specifically, on page 35, lines 1 to 11, applicants indicated, for example, that the "curved longitudinal support member 40 has a centerline 45 (parallel to the longitudinal axis 11 of the graft sleeve 10 halfway between the first and second degrees 41, 43 on the graft sleeve 10)." The second term is also defined with respect to the centerline, as defined in the specification, for example, at page 10, lines 23 to 24, page 15, lines 20 to 24, page 35, lines 6 to 11. A significant amount of description is provided so that one having ordinary skill in the art could understand what appellants mean when they use the words "centerline" and the concept of symmetry about that centerline.

Based upon this authority, the Examiner's contention, at lines 4 to 6 of page 5, that this term is merely a relative degree can find no basis for support and must be rejected because it contravenes applicants' defined meaning.

In complete contrast to the curved supporting member of the invention that is substantially symmetrical to the centerline, Van Schie **always has its elastic supporting material 8 disposed along a single axis and there is no suggestion that this material 8 deviates therefrom in any way** -- in other words, the Van Schie member 8 is absolutely straight and extends in a straight line *along* the longitudinal axis of the stent. See Van Schie at FIGS. 1 and 2 and paragraph 0045 (Note: anchor wire 70 in FIG. 7 is removed from the stent as set forth in paragraph 0056). An absolutely straight member is not analogous to the curved longitudinal support member of claims 1 and 15. Thus, the rejection of claims 1 and 15 under Section 102 fails.

For all of the reasons set forth above, claims 1, 15, 16, 18, 20, 25, and 28 are patentable over the cited art. The dependent claims are patentable as well because they all are ultimately dependent on one of these claims.

**4. Van Schie Does Not Disclose Features of Many Dependent Claims**

As set forth above, "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d at 1477 (emphasis added by appellants). There are many of the dependent claims for which Van Schie does not even hint at, let alone specifically describe, features contained therein. These dependent claims are discussed in the following text.

**a. Van Schie Does Not Disclose Features Relating to a Curved Shape of the Longitudinal Support Member**

Claim 3 provides that the "longitudinal support member has a flattened S-shape" and claim 4 provides that the "longitudinal support member has a partial helix shape." Likewise, claim 5 provides that the "longitudinal support member is curved with substantially asymptotic ends" and claim 10 provides that the "longitudinal support member is pre-formed in said curved shape." Each of these features describes a configuration of the longitudinal support member of the present invention. None of these features are suggested in any way, let alone described, in Van Schie. With respect to claim 40, the support member has a shape that "is substantially reverse-mirror symmetrical with respect to said centerline." Nowhere does Van Schie disclose or suggest such a shape. Therefore, Van Schie cannot be said to fully anticipate the features of these dependent claims.

**b. Van Schie Does Not Disclose Features Relating to a Looped End of the Longitudinal Support Member**

Claim 12 discloses a longitudinal support member having "a looped end with a curved longitudinal extremity" and claim 13 provides the support member with "two looped ends each with curved longitudinal extremities." Nowhere does Van Schie disclose or suggest such a shape to the ends of a support member. Therefore, Van Schie cannot be said to fully anticipate the features of these dependent claims.

**c. Van Schie Does Not Disclose Features Relating to the Length of the Longitudinal Support Member**

The text above describes why the present invention provides a gimbal and why Van Schie nowhere discloses or suggest such a gimbal. Claims 14 and 26 provide features relating to such

a gimbal. More specifically, claim 14 provides that the "longitudinal support member is shorter than said structural framework," and claim 26 provides that the "support member is connected to said graft body without touching said inner stents." Nowhere does Van Schie disclose or suggest such a length of a support member. Therefore, Van Schie cannot be said to fully anticipate the features of these dependent claims.

**d. Van Schie Does Not Disclose Features Relating to the Apices of a Stent**

Claims 48, 50, 52, 54, 56, 58, and 60 each provide that a "distal-most stent has at least one more apex than another of said at least two stents" of the vascular repair device, these other stents also having apices. Nowhere does Van Schie suggest, let alone disclose, this feature. Therefore, Van Schie cannot be said to fully anticipate the features of these claims.

**e. Van Schie Does Not Disclose Features Relating to a Stent Cross-Section**

Claims 65, 70, 75, 80, 85, 90, and 95 each provide that the:

> graft body has a longitudinal extent defining a longitudinal direction; and
>
> said stents have a substantially linear profile in said longitudinal direction.

Similarly, claims 66, 71, 76, 81, 86, 91, and 96 each provide that the "stents have a linear longitudinal profile." The profile mentioned in these fourteen claims is described with regard to FIGS. 2, 3, 5, and 7, for example.

Another feature relevant to the linear profile is the cross-sectional shape of the stents. Claims 67, 71, 72, 77, 82, 87, 92, and 97 each provide that the "stents have a circular cross-sectional shape."

This cross-sectional shape, like the linear longitudinal profile mentioned above, is described with regard to FIGS. 2, 3, 5, and 7, for example.

Nowhere does Van Schie suggest, let alone disclose, any of these features. Therefore, Van Schie cannot be said to fully anticipate any of the features of these claims.

For all of the reasons set forth above, the dependent claims mentioned herein are not anticipated by Van Schie. Accordingly, the Section 102 rejection of these claims must be reversed.

### D. White in view of Jayaraman Does Not Render Obvious Any of the Remaining Claims under 35 U.S.C. § 103(a).

Initially, it is noted that the Examiner admits "White et al. fail to disclose a longitudinal support member." Thus, White clearly is missing a required element of each of the above claims.

In an attempt to make up for this clear deficiency and complete the rejection, the Examiner must *add* a feature of Jayaraman to White. Specifically, the Examiner states that "Jayaraman teaches (Fig. 8) a longitudinal support member 53 ..." To support this combination, the Examiner merely states: "It would have been obvious to one of ordinary sill in the art to use curve longitudinal support members as taught by Jayaraman in the stent graft of White et al. such that it provides more support to the vessel walls and assist in expansion." Office action at page 5. **No further statements or proof are provided by the Examiner at all.** In fact, the entire rejection of all sixty-six (66) claims is set forth in a single paragraph of 16 lines.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be '**clear and particular.**'" *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). There is no "clear and particular" teaching or suggestion in Jayaraman to incorporate the features of White, and there is no teaching or suggestion in White to incorporate the features of Jayaraman.

In establishing a *prima facie* case of obviousness, it is **incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem

from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the applicants' disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). **In the six (6) lines where the Examiner discusses Jayaraman, the Examiner provides absolutely no reason why one** of ordinary skill in the art **would have been led to modify** Jayaraman or White or to combine Jayaraman's and White's teachings to arrive at the claimed vascular repair device invention.

**The Examiner has the burden for satisfying the above requirements.** But, the **Examiner has not shown the requisite motivation** from some teaching, suggestion, or inference in Jayaraman or White or from knowledge available to those skilled in the art.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614,1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the present application. "It is impermissible, however, simply to

engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. . . . The references **themselves** must provide some teaching whereby the applicant's combination would have been obvious." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Here, no such teaching is present in the cited references. In fact, the teaching of Jayaraman would not be in a direction *towards* the suggested combination, it would be in the opposite direction because White is a Z-stent configuration; in such configuration, there are two or more circumferential supporting devices 17, 17a that radially support a tubular graft about its circumference. In complete contrast, Jayaraman is a tubular stent having a cylindrical fabric tube with multiple serpentine shaped *longitudinal* pieces that are fastened to the tube along *longitudinal lines*, not circumferentially.

Jayaraman is a stent, it does not have stents (plural) as defined in the instant application (see page 2, lines 9 to 14, citing U.S. Patent Nos. 5,282,824 and 5,507,771) and as known and referred to in the art. In particular, Jayaraman does not have the **"at least two stents"** required by claims 1, 15, 16, or 18, the **"at least two pairs of stents"** required by claims 20 or 25, or the **"at least three stents"** required by claim 28. In fact, to have "at least two stents" in the Jayaraman disclosure would mean that there would have to be two entire tubular structures each having the sets of serpentine connecting pieces. Nowhere does Jayaraman disclose entirely duplicating, triplicating, or quadrupling itself.

Jayaraman does not even relate to prostheses that use stents or, especially, z-stents. Instead, the entire Jayaraman device *is* a stent. Merely because the title of Jayaraman uses the word "stent"

does not mean that it relates to the kind of technology that utilizes the plurality of circumferential z-stents that is described in detail in the instant application. Accordingly, there can be no motivation anywhere within Jayaraman to implement the *tubular* stent technology of Jayaraman in a *z-stent intraluminal graft* disclosed in White.

The Examiner contends that the S-shaped connecting pieces 53 of Jayaraman would "provide more support to the vessel walls and assist in expansion" if added to White. This conclusion, however, is unsupported and incorrect. There would be no assistance in the expansion of the White stent graft if the connecting pieces 53 of Jayaraman were added to White. **In fact, the opposite is true** because any relatively rigid pieces attached to the graft tube of White would *prevent expansion*, not "assist in expansion" as asserted by the Examiner. If such a combination was hypothetically made, at best, there would be *no* affect on expansion and, at worst, expansion would be *hindered* by adding the rigid pieces of Jayaraman to White.

Jayaraman clearly discloses that many of the connecting pieces 53 must be disposed about the circumference of the tubular body. There is no suggestion to use only one of the connecting pieces 53 in Jayaraman in any way and, especially, there is no hint or suggestion in White to make such a drastic change in the Jayaraman device. In fact, if one were to add multiple connecting pieces 53 to White (which is what is actually disclosed by Jayaraman), the resulting hypothetical stent graft would be significantly or dangerously rigid about its longitudinal axis and would, therefore, *not be able to be implanted in curved vessels*! Such a hypothetical combination, therefore, would *defeat White's intended purpose.*

The Examiner cited FIG. 8 of Jayaraman for the feature that is added to White to form the combination rejection. It is significant to note that there is nothing to show or suggest in Jayaraman that the FIG. 8 prosthesis could ever function as a stent graft or even relate to a stent graft because there is no force applied by the connecting piece 53 that could ever assist in keeping the lumen of the material fabric tube 51 open after being implanted in a vessel. As such, the combination of these two different features cannot be supported.

**1. The Combined References Do Not Suggest the Features of Claims 1 or 15**

Claims 1 and 15 provide that the support member is substantially symmetrical with respect to a longitudinal axis of the device. In comparison, White has no support members. See Office action at page 4, line 6.

While Jayaraman has devices 53 extending longitudinally along the material, they are not symmetrical about the longitudinal axis as set forth in the claims. As can be clearly seen in every figure of Jayaraman, the two extreme ends of the connecting pieces 53 end are always on the same side. Therefore, with respect to a longitudinal extent of the connecting piece 53, there is no way that the Jayaraman connecting pieces 53 can be considered symmetrical as defined in claims 1 and 15. See also Jayaraman at FIGS. 1, 3, 4, 7, and 8.

The Examiner contends on page 4 of the final Office action at lines 14 to 18:

> Regarding the limitations that the support is symmetrical to the centerline of the graft, it is being interpreted that the middle of the graft is the centerline and thus half of the support is on one side and the other half on the opposite side. The support members [53] can also be said to be [be] symmetrical with respect to a centerline through itself." (Emphasis added by applicants.)

This statement is not only unsupported, it is contrary to the disclosure and meaning of "centerline" and "symmetrical" set forth in the present application. Here, the Examiner is changing the definitions of terms that relate to and define the features of the present invention, which definitions are provided in the cited specification excerpts set forth above.

Further, the claims, themselves, set forth the symmetrical relationship of the support member – that it is symmetrical with respect to the "longitudinal axis" of the graft body (a relationship that is consistent with the disclosure and is inconsistent with the Examiner's changes). Simply put, in the exemplary embodiments that relate to the claims of the present application, a part of the curved longitudinal support member is on one side of the centerline thereof and of the longitudinal axis and another part of the support member is on the other side, and these parts are symmetrical with respect to the longitudinal axis. The Examiner mischaracterizes this disclosure and the definition towards an entirely different meaning -- that the support members are symmetrical about a *transverse* centerline "through itself" (i.e., through a line that is *orthogonal to* the longitudinal extent of the connecting pieces 53. However, use of the word "longitudinal" in the claims of the present application requires the symmetry to be with respect to the longitudinal extent and not the transverse extent.

**2. The Combined References Do Not Suggest the Features of Claim 16**

The Examiner contends with regard to claim 16 that the connecting pieces 53 have "looped ends 55." As set forth above, these ends are merely rounded. They do not have and are not "curved longitudinal extremit[ies]" as set forth in claim 16. The specification of the present application at page 37 provides:

> the end of the longitudinal support member loops 47 back upon itself such that the end of the longitudinal support member along the axis of the stent graft is not sharp and, instead, presents an exterior of a circular or oval shape when viewed from the ends 12, 14 of the graft sleeve 10. Such a configuration substantially prevents the possibility of tearing the vessel wall and also provides additional longitudinal support at the oval shape by having two longitudinally extending sides of the oval 47.

There is a difference between "rounded" and curved. As "curved" is used in the present application, it means that the end traverses a curve. In contrast, the ends of 53 are straight with rounded edges. The rounded ends of the connecting pieces 53 are not curved – in fact, as compared to the remainder of the pieces 53, they are straight -- and do not traverse a curve and, therefore, cannot suggest the curved extremities disclosed in claim 16. The Examiner contends that the part labeled "55" in Jayaraman is such a curved end. It is respectfully submitted that this reference numeral merely identifies the "holes" in the end of the pieces 53 for receiving a suture to connect the piece 53 to the graft. See Jayaraman at col. 4, line 24.

### 3. The Combined References Do Not Suggest the Features of Claims 18, 20, 25, or 28

Claims 18, 20, 25, and 28 each include features where a longitudinal support member has a length smaller than a distance between two stents to create a gimbal. Neither Jayaraman nor White disclose or even suggest such a feature and, therefore, a combination of the two also do not suggest such a feature. The arguments with regard to the gimbal feature set forth above are hereby incorporated by reference herein to prevent redundancy. Simply put, to have a gimbal at one end of a stent graft, there is a structure including a longitudinal support member **terminating at or prior to** a second-to-last circumferential stent (i.e., Z-stent) on that end. Jayaraman is entirely unrelated to circumferential stents. Thus, it can contribute nothing towards the

suggestion of claims 18, 20, 25, or 28. With regard to White, the Examiner admits that it is entirely silent on the subject of supporting members ("White et al. fail to disclose a longitudinal support member." Final Office Action at 4). Therefore, there is no way to have a conclusion where either White, Jayaraman, or the combination thereof can suggest any aspect of the features of claims 18, 20, 25, or 28.

Clearly, the combination of Jayaraman and White do not suggest the vascular repair device as recited in any of claims 1, 15, 16, 18, 20, 25, or 28 of the present application.

**4. The Combination Does Not Disclose Features of Many Dependent Claims**

As set forth above, when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation in the prior art to make the selection made by the applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985). Many of the features of the dependent claims are not suggested by either White, Jayaraman, or the combination of the two.

**1. The Combination Does Not Disclose Features Relating to a Curved Shape of the Longitudinal Support Member**

Claim 3 provides that the "longitudinal support member has a flattened S-shape" and claim 4 provides that the "longitudinal support member has a partial helix shape." Likewise, claim 5 provides that the "longitudinal support member is curved with substantially asymptotic ends" and claim 10 provides that the "longitudinal support member is pre-formed in said curved shape." Each of these features describes a configuration of the longitudinal support member of the present invention. None of these features are suggested in any way in White and/or

Jayaraman. With respect to claim 40, the support member has a shape that "is substantially reverse-mirror symmetrical with respect to said centerline." Nowhere do White and/or Jayaraman disclose or suggest such a shape. Therefore, neither White, Jayaraman, nor the combination of the two renders obvious the features of these dependent claims.

**b. The Combination Does Not Disclose Features Relating to a Looped End of the Longitudinal Support Member**

Claim 12 discloses a longitudinal support member having "a looped end with a curved longitudinal extremity" and claim 13 provides the support member with "two looped ends each with curved longitudinal extremities." Nowhere do White and/or Jayaraman suggest such a shape to the ends of a support member. Therefore, neither White, Jayaraman, nor the combination of the two renders obvious the features of these dependent claims.

**c. The Combination Does Not Disclose Features Relating to the Length of the Longitudinal Support Member**

The text above describes why the present invention provides a gimbal and why White and/or Jayaraman nowhere suggest such a gimbal. Claims 14 and 26 provide features relating to such a gimbal. More specifically, claim 14 provides that the "longitudinal support member is shorter than said structural framework," and claim 26 provides that the "support member is connected to said graft body without touching said inner stents." Nowhere do White and/or Jayaraman suggest such a length of a support member. Therefore, neither White, Jayaraman, nor the combination of the two renders obvious the features of these dependent claims.

**d. The Combination Does Not Disclose Features Relating to the Apices of a Stent**

Claims 48, 50, 52, 54, 56, 58, and 60 each provide that a "distal-most stent has at least one more apex than another of said at least two stents" of the vascular repair device, these other stents also having apices. Nowhere do White and/or Jayaraman suggest this feature. Therefore, neither White, Jayaraman, nor the combination of the two renders obvious the features of these dependent claims.

**e. The Combination Does Not Disclose Features Relating to a Stent Cross-Section**

Claims 65, 70, 75, 80, 85, 90, and 95 each provide that the:

> graft body has a longitudinal extent defining a longitudinal direction; and
>
> said stents have a substantially linear profile in said longitudinal direction.

Similarly, claims 66, 71, 76, 81, 86, 91, and 96 each provide that the "stents have a linear longitudinal profile." The profile mentioned in these fourteen claims is described with regard to FIGS. 2, 3, 5, and 7, for example.

Another feature relevant to the linear profile is the cross-sectional shape of the stents. Claims 67, 71, 72, 77, 82, 87, 92, and 97 each provide that the "stents have a circular cross-sectional shape." This cross-sectional shape, like the linear longitudinal profile mentioned above, is described with regard to FIGS. 2, 3, 5, and 7, for example.

Nowhere do White and/or Jayaraman suggest any of these features. Therefore, neither White, Jayaraman, nor the combination of the two renders obvious the features of these dependent claims.

For all of the reasons set forth above, the dependent claims mentioned herein are rendered obvious by White and/or Jayaraman. Accordingly, the Section 103 rejection of these claims must be reversed.

## CONCLUSION:

Van Schie does not anticipate any of claims 1, 15, 16, 18, 20, 25, or 28. These claims are, therefore, allowable over the prior art. Insofar as claims 2, 5, 6, 10, 11, 14, 17, 21, 24, 26, 27, 29, 40 to 42, 44 to 47, 49, 51, 55, 57, 59, 65 to 67, 70 to 72, 75 to 77, 85 to 87, 90 to 92, and 95 to 97 are ultimately dependent upon one of the independent claims, these claims are allowable as well.

White in view of Jayaraman does not render obvious any of claims 1, 15, 16, 18, 20, 25, or 28. These claims are, therefore, allowable over the prior art. Insofar as claims 2 to 6, 10 to 14, 17, 19, 21, 24, 26, 27, 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 are ultimately dependent upon one of the independent claims, these claims are allowable as well.

The honorable Board is, therefore, respectfully urged to reverse the final rejection of the Primary Examiner and to allow claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97.

Respectfully submitted,

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Date: December 18, 2006

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Appendix - Appealed Claims:

1. A vascular repair device, comprising:

a tubular graft body having a longitudinal axis;

a structural framework having at least two stents connected to said graft body; and

a curved longitudinal support member connected to said graft body and having a centerline parallel to said longitudinal axis, said support member being substantially symmetrical with respect to said longitudinal axis.

2. The vascular repair device according to claim 1, wherein said longitudinal support member is of a material selected from the group consisting of nitinol, stainless steel, biopolymers, Cobalt Chrome, and titanium alloys.

3. The vascular repair device according to claim 1, wherein said longitudinal support member has a flattened S-shape.

4. The vascular repair device according to claim 1, wherein said longitudinal support member has a partial helix shape.

5. The vascular repair device according to claim 1, wherein said longitudinal support member is curved with substantially asymptotic ends.

6. The vascular repair device according to claim 1, wherein said longitudinal support member is connected to said graft body independent of said structural framework.

10. The vascular repair device according to claim 1, wherein said longitudinal support member is pre-formed in said curved shape.

11. The vascular repair device according to claim 1, wherein said longitudinal support member has rounded ends.

12. The vascular repair device according to claim 1, wherein said longitudinal support member has a looped end with a curved longitudinal extremity.

13. The vascular repair device according to claim 1, wherein said longitudinal support member has two looped ends each with curved longitudinal extremities.

14. The vascular repair device according to claim 1, wherein said longitudinal support member is shorter than said structural framework.

15. A vascular repair device, comprising:

a tubular graft body having a longitudinal axis;

a structural framework having at least two stents connected to said tubular graft body; and

a curved longitudinal support member connected to said graft body independent of said structural framework and having a centerline parallel to said longitudinal axis, said support member being substantially symmetrical with respect to said longitudinal axis.

16. A vascular repair device, comprising:

a tubular graft body;

a structural framework having at least two stents connected to said tubular graft body; and

a longitudinal support member having two ends, at least one of said ends having a curved longitudinal extremity.

17. The vascular repair device according to claim 16, wherein said support member is curved.

18. A vascular repair device, comprising:

a tubular graft body having a proximal end and a distal end;

a structural framework having at least two stents each respectively connected to said tubular graft body adjacent said proximal end and said distal end and defining a separation distance therebetween; and

a longitudinal support member shorter than said separation distance and being connected to said graft body between said at least two stents to form a gimbal at at least one of said proximal and distal ends of said graft body.

19. The vascular repair device according to claim 18, wherein said support member is curved.

20. A vascular repair device, comprising:

a tubular graft body having a proximal end and a distal end;

a structural framework having at least two pairs of stents each respectively connected to said graft body adjacent said proximal end and said distal end, said stents of each of said pairs of stents being separated from one another at said graft body to define a respective outer stent and a respective inner stent; and

a longitudinal support member connected to said graft body and extending between:

at least said inner stent of a first of said two pairs of stents; and

at least said outer stent of a second of said two pairs of stents.

21. The vascular repair device according to claim 20, wherein said support member is connected to said graft body between both of said inner stents of said two pairs of stents.

24. The vascular repair device according to claim 20, wherein said support member is curved.

25. A vascular repair device, comprising:

a tubular graft body having a proximal end and a distal end;

a structural framework having at least two pairs of stents each respectively connected to said graft body adjacent said proximal end and said distal end, said stents of each of said pairs of stents being separated from one another at said graft body to define a respective outer stent and a respective inner stent; and

a curved longitudinal support member having two ends and being connected to said graft body between both of said inner stents of said two pairs of stents.

26. The vascular repair device according to claim 25, wherein said support member is connected to said graft body without touching said inner stents.

27. The vascular repair device according to claim 25, wherein said support member is connected to said graft body to touch at least one of said inner stents.

28. A vascular repair device, comprising:

a tubular graft body having first and second ends;

a structural framework having at least three stents, two of said stents being connected to said tubular graft body adjacent said first end, said two stents being separated from one another on said graft body to define an outer stent and an inner stent, a third of said stents being connected to said tubular graft body adjacent said second end; and

a longitudinal support member having two ends and being connected to said graft body between said inner stent and said third stent without touching said inner stent and said third stent.

29. The vascular repair device according to claim 28, wherein said support member is curved.

40. The vascular repair device according to claim 1, wherein said support member is substantially reverse-mirror symmetrical with respect to said centerline.

41. The vascular repair device according to claim 15, wherein said support member has a centerline and is substantially symmetrical with respect to said centerline.

42. The vascular repair device according to claim 17, wherein said support member has a centerline and is substantially symmetrical with respect to said centerline.

43. The vascular repair device according to claim 19, wherein said support member has a centerline and is substantially symmetrical with respect to said centerline.

44. The vascular repair device according to claim 24, wherein said support member has a centerline and is substantially symmetrical with respect to said centerline.

45. The vascular repair device according to claim 25, wherein said support member has a centerline and is substantially symmetrical with respect to said centerline.

46. The vascular repair device according to claim 29, wherein said support member has a centerline and is substantially symmetrical with respect to said centerline.

47. The vascular repair device according to claim 1, wherein said graft body has a diameter at least as large as a diameter of a vessel into which said graft body is to be placed.

48. The vascular repair device according to claim 1, wherein:

said at least two stents each have apices;

said structural framework has a distal-most stent; and

said distal-most stent has at least one more apex than another of said at least two stents.

49. The vascular repair device according to claim 15, wherein said graft body has a diameter at least as large as a diameter of a vessel into which said graft body is to be placed.

50. The vascular repair device according to claim 15, wherein:

said at least two stents each have apices;

said structural framework has a distal-most stent; and

said distal-most stent has at least one more apex than another of said at least two stents.

51. The vascular repair device according to claim 16, wherein said graft body has a diameter at least as large as a diameter of a vessel into which said graft body is to be placed.

52. The vascular repair device according to claim 16, wherein:

said at least two stents each have apices;

said structural framework has a distal-most stent; and

said distal-most stent has at least one more apex than another of said at least two stents.

53. The vascular repair device according to claim 18, wherein said graft body has a diameter at least as large as a diameter of a vessel into which said graft body is to be placed.

54. The vascular repair device according to claim 18, wherein:

said at least two stents each have apices;

said structural framework has a distal-most stent; and

said distal-most stent has at least one more apex than another of said at least two stents.

55. The vascular repair device according to claim 20, wherein said graft body has a diameter at least as large as a diameter of a vessel into which said graft body is to be placed.

56. The vascular repair device according to claim 20, wherein:

said stents each have apices;

one of said pairs of stents adjacent said distal end has a distal-most stent; and

said distal-most stent has at least one more apex than another of said stents.

57. The vascular repair device according to claim 25, wherein said graft body has a diameter at least as large as a diameter of a vessel into which said graft body is to be placed.

58. The vascular repair device according to claim 25, wherein:

said stents each have apices;

one of said pairs of stents adjacent said distal end has a distal-most stent; and

said distal-most stent has at least one more apex than another of said stents.

59. The vascular repair device according to claim 28, wherein said graft body has a diameter at least as large as a diameter of a vessel into which said graft body is to be placed.

60. The vascular repair device according to claim 28, wherein:

said stents each have apices;

one of said stents is a distal-most stent; and

said distal-most stent has at least one more apex than another of said stents.

65. The vascular repair device according to claim 1, wherein:
said graft body has a longitudinal extent defining a longitudinal direction; and
said stents have a substantially linear profile in said longitudinal direction.

66. The vascular repair device according to claim 65, wherein said stents have a linear longitudinal profile.

67. The vascular repair device according to claim 65, wherein said stents have a circular cross-sectional shape.

70. The vascular repair device according to claim 15, wherein:

said graft body has a longitudinal extent defining a longitudinal direction; and

said stents have a substantially linear profile in said longitudinal direction.

71. The vascular repair device according to claim 70, wherein said stents have a linear longitudinal profile.

72. The vascular repair device according to claim 70, wherein said stents have a circular cross-sectional shape.

75. The vascular repair device according to claim 16, wherein:

said graft body has a longitudinal extent defining a longitudinal direction; and

said stents have a substantially linear profile in said longitudinal direction.

76. The vascular repair device according to claim 75, wherein said stents have a linear longitudinal profile.

77. The vascular repair device according to claim 75, wherein said stents have a circular cross-sectional shape.

80. The vascular repair device according to claim 18, wherein:

said graft body has a longitudinal extent defining a longitudinal direction; and

said stents have a substantially linear profile in said longitudinal direction.

81. The vascular repair device according to claim 80, wherein said stents have a linear longitudinal profile.

82. The vascular repair device according to claim 80, wherein said stents have a circular cross-sectional shape.

85. The vascular repair device according to claim 20, wherein:
said graft body has a longitudinal extent defining a longitudinal direction; and
said stents have a substantially linear profile in said longitudinal direction.

86. The vascular repair device according to claim 85, wherein said stents have a linear longitudinal profile.

87. The vascular repair device according to claim 85, wherein said stents have a circular cross-sectional shape.

90. The vascular repair device according to claim 25, wherein:
said graft body has a longitudinal extent defining a longitudinal direction; and
said stents have a substantially linear profile in said longitudinal direction.

91. The vascular repair device according to claim 90, wherein said stents have a linear longitudinal profile.

92. The vascular repair device according to claim 90, wherein said stents have a circular cross-sectional shape.

95. The vascular repair device according to claim 28, wherein:
said graft body has a longitudinal extent defining a longitudinal direction; and
said stents have a substantially linear profile in said longitudinal direction.

96. The vascular repair device according to claim 95, wherein said stents have a linear longitudinal profile.

97. The vascular repair device according to claim 95, wherein said stents have a circular cross-sectional shape.